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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,718	01/04/2002	Ralph Evan McGinnis	2DLSM&R12/01	7724
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Robert McGinnis				
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			EXAMINER	
			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	
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			11/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/037,718

Applicant(s)

MCGINNIS ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2007 and 09 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 91-166 is/are pending in the application.
- 4a) Of the above claim(s) 140-166 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 91-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2007 has been entered.

Applicants' responses, filed 10/02/2007 and 02/09/2007, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

### *APPLICANT'S ELECTION*

Applicant's supplementary election with traverse of Group II drawn to oligonucleotides (claims 16-19, 21, 24, 26-34, 68-80, 89, and 90), filed 08/16/2007, is acknowledged. Applicant has subsequently cancelled claims 1-90 and newly submitted claims 91-166. The traversal on the grounds that groups II and IV should both be examined as they are "attached" has been considered but is not persuasive for reasons set forth in the previous restriction requirement, namely that Groups II and IV are directed to different statutory categories of inventions. The requirement is still deemed proper and is therefore made FINAL.

Claims 140-166 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic

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or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/16/2007.

*CLAIMS UNDER EXAMINATION*

Newly submitted claims 91-139 are herein under examination. Claims 1-90 have been cancelled.

*PRIORITY*

Priority to US Application 09/947,768, filed 9/5/2001, has been acknowledged.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 91-139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claim 91 are also rejected due to said dependence.

Claim 91 is drawn to a composition comprising oligonucleotides complementary to covering markers "chosen so that a CL-F region is systematically covered by the covering markers,..., the CL-F having to orthogonal dimensions of chromosomal location...". As a result, it is unclear (a) in what way the method of choosing the covering markers further limits the

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claimed composition, and (b) in what way recited limitations of the CL-F further limit the claimed composition. As a result of the confusing claim language, the Examiner cannot determine what limitation and/or elements recited in the claim constitute the claimed "composition" such that it is clear what the applicant is seeking patent protection for, and such that a search of the prior art may be conducted. Clarification is requested via clearer claim language.

Claim 92: It is unclear (a) in what way said limitations of the CL-F further limit the claimed composition, (b) in what way the recited limitations of the population further limit the claimed composition, and (c) in what way "the largest chromosomal length, computer by any method, for which linkage disequilibrium has been observed..." further limits the claimed composition. Clarification is requested via clearer claim language.

Claim 94: It is unclear (a) in what way said limitations of the CL-F further limit the claimed composition, and (b) in what way the recited limitations of the population further limit the claimed composition. Clarification is requested via clearer claim language.

Claims 104, 108, and 110 are rejected for similar reasons set forth above. Namely, it cannot be determined in what the recited limitations and/or elements are intended to further limit the claimed composition. Clarification is requested via clearer claim language.

Claims 91-94, 104, 108, and 110: It is unclear as to the metes and bounds of "CL-F region" and a "CL-F map" such that an artisan would know what constitutes these limitations. Clarification is requested via clearer claim language.

Claims 111-123 and 133-139 are drawn to a "composition, wherein an apparatus comprises copies of sets of oligonucleotides..." and recites further limitations of the apparatus in the claims. It is noted that applicant's have explicitly stated that the apparatus and the composition are not independent and distinct in the remarks filed 8/16/2007. However, it is unclear whether the claimed composition is intended to comprise a oligonucleotides or an

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apparatus or both. If the later, it is unclear in what way the apparatus and composition are related. It is noted that a single claim that recites both a product and apparatus (i.e. for producing the product) in the same claim are considered indefinite [MPEP 2173.05]. Clarification is requested via clearer claim language.

### **CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 91-139 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claims 91-139 are drawn to compositions comprising one or more copies of a set of oligonucleotides being complementary to be-allelic covering markers, wherein the markers are for a species of creatures. Furthermore, claims 125-139 limit the species of creatures to human beings. As the claims are directed to compositions, the method or apparatus by which these compositions are selected or created has no restrictive effect on the instant compositions (i.e. a product is a product). Therefore, the composition claims are not statutory as they "read" on the naturally occurring genome of any "creature", which inherently contains sets of oligonucleotides, polymorphisms, and allelic markers. Therefore the instant claims are directed to nonstatutory subject matter as the broadest reasonable interpretation of the claimed invention encompasses a human being.

*PRIOR ART REJECTION OF INDEFINITE CLAIMS*

In view of the indefiniteness and lack of clarity in the instant claims, as set forth in the 35 USC 112 2nd rejections above, the Examiner has had difficulty in properly interpreting instant claims. However, to avoid piecemeal prosecution and to give applicant a better appreciation for relevant prior art if the claims are redrafted to avoid the 35 USC 112 2nd rejections, the Examiner has broadly interpreted the claims for purposes of applying the following prior art rejections.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 91-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US 5945522; Issued Aug. 31, 1999; Filed Dec. 22, 1997), in view Kruglyak et al. (Am. J. Hum. Genet., 1995, Vol. 57, p.439-454).

Cohen teaches a gene associated with prostate cancer in humans. In particular, the invention provides oligonucleotides which are used to detect the presence of bi-allelic sites that

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are in linkage disequilibrium with the PG1 gene for use in determining the risk of prostate cancer [Col. 6, lines 5-25]. Bi-allelic sites are systematically verified by comparing the sequences of both strands of each pool (i.e. enabling selection of complementary markers) [See Col. 16, Example 2]. Major and minor allele frequencies are determined, wherein the frequency of bi-allelic polymorphisms detected is  $0.3 \pm 0.05$  for the minor allele, as verified by sequencing pools of known allelic frequencies. Thus, the bi-allelic markers selected by this method will be "informative bi-allelic markers" since they have a frequency of 0.3 to 0.5 for the minor allele and 0.5 to 0.7 for the major allele. Methods are also provided for the selection of complementary sequences [Col. 5, lines 40-50]. Quantitative analysis of gene expression may also be performed using arrays, wherein the term array means a one dimensional, two dimensional, or multidimensional arrangement of a plurality of nucleic acids of sufficient length to permit specific detection of expression of mRNAs capable of hybridizing thereto [See Example 12]. Figures 2, 3, and 4 aggregate linkage analysis results with sequencing results for determining the distance between markers to be estimated. Therefore, Cohen teaches critical limitation of claims 91-94 and 104-166.

Cohen does not specifically teach limitations directed to the CL-F map or CL-F region (broadly interpreted as a chromosomal genetic map) as recited in claims 91-94, or specific limitations of allele frequencies as in claims 95-103. However, Cohen clearly teaches minor allele frequencies, set forth above. Therefore, the Examiner interprets the limitations of claims 95-103 to be obvious variations of known techniques and invites the applicant to demonstrate the novel or unobvious difference between the claimed limitations and those used in the prior art.

Kruglyak teaches the use of a chromosomal genetic map of biallelic markers in linkage studies and provides an computer package (MAPMAKER) for multipoint analysis using dozens



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of markers [See: Abstract, p.441] wherein the map is a two-dimensional map [Fig. 1] and wherein the markers cover various chromosomal positions [Fig. 2]. The program requires pedigree information, genotype information, and a map file of location and frequencies of genetic markers [p.441, Col. 2, MAPMAKER]. Kruglyak also suggest obtaining good estimates of allele frequencies from appropriate populations.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the compositions comprising oligonucleotides attached to solid support taught by Cohen in combination with the chromosomal genetic mapping software taught by Kruglyak, for purposes of using an automated software package that allows rapid analysis of sib-pair data in a user-friendly format [p.452, Col. 1]. One of ordinary skill in the art would have been motivated to combine the above teachings in order improve cancer diagnosis by using software designed to maximize the amount of inheritance information extracted from each location in the genome, as suggested by Kruglyak [Summary], resulting in the practice of the instantly claimed invention with predictable results. For these reasons, the instant claims do not recite any new element or new function or unpredictable result.

## CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*John S. Brusca* 29 October 2007  
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